



NIH Update: Spring 2002

- Graduate Student Compensation
- F&A Costs on Foreign Grants or foreign consortium arrangements
- Salary Cap
- Human Subject Education
- Sharing Research Data
- NIH Regional Seminars



Graduate Student Compensation

- Ties to compensation on research grants to the Zero level NRSA Postdoc stipend in effect at the time of the award. (\$31,092).
- Compensation continues to include: Salary/Wages, Fringe Benefits and Tuition Remission.
- If submitting an itemized budget, grantees should request actual institutional-based compensation and include justification.



Graduate Student Compensation

—(cont.)

- **NIH staff will review and determine appropriate level at the time of award.**
- **Revised budgets (modular or itemized) will not be accepted solely to adjust this compensation level.**
- **No adjustments will be made to non-competing award levels or future years.**
- **Effective with awards issued on or after 12/10/2001.**
- **No adjustments will be made to FY2002 awards issued before that date.**
- **Grantees may rebudget to accommodate the higher level.**



F&A Costs For Foreign And International Organizations

- Grants to foreign organizations and foreign consortium participants
 - Competing Applications only
 - 8% F& A based on Direct Costs, Less Equipment
 - Non-competing progress reports: Funds may be rebudgeted.
 - Effective 10/01/2001



Extramural Salary Cap

- FY2002 is the 13th consecutive year for the salary cap.
- Restricts the amount of **direct salary** under a grant or contract to Executive Level 1 of the Federal Executive Pay Scale. Currently at a rate of **\$166,700** per year. (NIH Guide 1/25/2002)



Requirement for Education in the Protection of Human Subjects

- NIH education requirement remains in effect.
- Key personnel involved in human subject research must receive training in the responsible conduct of research
 - Key personnel are defined as those staff who are significantly involved in the design and conduct of the research.



Requirement for Education in the Protection of Human Subjects

■ Competing Application:

- Provide description of education completed for each key person.
- Submission in cover letter signed by the Institutional official. PI signature not required.
- JIT procedures apply.



Requirement For Education In The Projection of Human Subjects

■ Non-Competing Application

- Description of education must be included in annual progress reports for new key personnel or if not previously reported.



Requirement For Education In The Protection Of Human Subjects

■ Recent Changes

- For Letter – signature of PI is optional
- For Consortium Participants – NIH I/Cs can restrict consortium participation pending receipt of documentation.
- Allowing start up of project when consortium activity can be delayed.
- See NIH Guide of 9/7/2001



Sharing Research Data

- 3 Month Comment Period 3/1 – 6/1/2002.
- Effective Date: Jan. 1, 2003
- NIH will expect the timely release and sharing of final research data for use by other researchers.
- NIH will require applicants to include a plan for data sharing or to state why data sharing is not possible.



What Do We Mean By Data?

- We mean final research data necessary to validate research findings.
- Research data does not include:
 - **Lab notebooks**
 - **Partial data sets**
 - **Preliminary analyses**
 - **Drafts of scientific papers**
 - **Plans for future research**
 - **Communications with colleagues**
 - **Physical objects, such as gels or lab specimens.**



This Will Apply To:

- Intramural scientists
- Extramural scientists seeking:
 - Grants, Cooperative Agreements
 - Contracts



What Kind Of Research Does This Apply To?

- **Data generated with support from NIH, including:**
 - **Basic Research**
 - **Clinical studies**
 - **Surveys**

Unless human research participant's identities cannot be protected.

Important to share: Unique data sets that cannot be readily replicated. Large, expensive data sets.



Will NIH Provide Support for Data Sharing?

- Yes.
- In application – budget and budget justification.
- Administrative Supplements.



Caveats For Studies Including Human Research Participants

- Investigators need to be cautious with:
 - Studies with very small samples
 - Studies collecting very sensitive data

However...

data can be shared *if*, safeguards exist to ensure confidentiality and protect the identity of subjects.



What Is Meant By Timely?

- No timeline specified. Will vary depending on nature of the data collected.
- Investigators who collected the data have a legitimate interest in benefiting from their investment of time and effort.
- Therefore, they could benefit from first and continuing use but not from prolonged exclusive use.



Why Share?

- Extends NIH policy on sharing research resources.
- Reinforces open scientific inquiry.
- Encourages diversity of analysis and opinion.
- Promotes new research.



How To Share Data

- Publications
- Share under the investigator's own auspices
- Place data sets in public archives
- Put data on a web site
- Suggestions?



What Will NIH Applicants Need To Do?

- Include a data sharing plan in application.
 - Statement of how data will be shared
 - If not, why?

Where in the application?

- End of research plan
- Budget, budget justification if requesting funds



For More Information...

- http://grants.nih.gov/grants/policy/data_sharing/index.htm



NIH Regional Seminars

- Michigan State University, East Lansing, Michigan: April 11-12, 2002
<http://www.vprgs.msu.edu/nih02/>
- University of Louisville, Louisville, Ky.: June 6 – 7, 2002
<http://research.louisville.edu/nih-regional.html>